Imfinzi® (durvalumab)
(Intravenous)

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I. Length of Authorization Δ [1,23,26]

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancer: Coverage will be provided for 3 doses.
- Non-Small Cell Lung Cancer (NSCLC) (single-agent use as consolidation therapy): Coverage will be provided for 6 months and may be renewed up to a maximum of 12 months of therapy.*
- Non-Small Cell Lung Cancer (NSCLC) (resectable disease): Coverage will be provided for a maximum of 12 weeks of neoadjuvant therapy and 48 weeks of adjuvant therapy.*
- Small Cell Lung Cancer (SCLC) (limited stage disease): Coverage will be provided for 6 months and may be renewed up to a maximum of 24 months of therapy.*
- Bladder Cancer: Coverage will be provided for a maximum of 12 weeks of neoadjuvant therapy and 32 weeks of adjuvant therapy.*
- Neoadjuvant treatment of Gallbladder Cancer: Coverage will be provided for a maximum of 6 months and may NOT be renewed

Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.		
Dosing Frequency	**Maximum length of therapy**	**Maximum number of doses**
2 weeks	1 year	26 doses
3 weeks	12 weeks	4 doses
4 weeks	32 weeks	8 doses
	48 weeks	12 doses
	1 year	13 doses
	2 years	26 doses

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- NSCLC, SCLC: 672 billable units (6,720 mg) every 84 days
- Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancer: 150 billable units (1,500 mg) every 28 days for 3 doses
- Biliary Tract Cancers & Ampullary Adenocarcinoma: 150 billable units (1,500 mg) every 21 days x 8 doses, then 150 billable units (1,500 mg) every 28 days
- Hepatocellular Carcinoma: 150 billable units (1,500 mg) every 28 days
- Cervical Cancer: 150 billable units (1,500 mg) every 21 days x 4 doses, then 150 billable units (1,500 mg) every 28 days
- Endometrial Cancer: 112 billable units (1,120 mg) every 21 days x 6 doses, then 150 billable units (1,500 mg) every 28 days
- Bladder Cancer: 150 billable units (1,500 mg) every 21 days x 4 doses, then 150 billable units (1,500 mg) every 28 days for 8 doses

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy unless otherwise specified **Δ**; **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,3-5,16,12e]

- Used as a single agent for consolidation therapy; **AND**
  - Patient has unresectable stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy; **OR**
  - Patient has unresectable stage II disease **Ω**; **AND**
    - Patient has performance status (PS) of 0-1; **AND**
    - Disease has not progressed after definitive concurrent or sequential platinum based chemoradiation; **AND**
    - Patient does not have EGFR exon 19 deletion or exon 21 L858R mutations; **OR**
- Used as neoadjuvant therapy **†**; **AND**
  - Patient has resectable disease (tumors ≥4 cm or node positive); **AND**
  - Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; **AND**
  - Patient has no known EGFR mutations or ALK rearrangements; **OR**
- Used adjuvant therapy; **AND**

- Used as a single agent following previous neoadjuvant durvalumab plus chemotherapy and surgery; **AND**
- Patient has no known EGFR mutations or ALK rearrangements **†**; **OR**

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with tumors that are negative for actionable molecular biomarkers*****(may be KRAS G12C mutation positive) and PD-L1 ≥ 1% to 49%; **OR**
      - Patients who have tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 < 1%; **OR**
      - Patients who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **AND**
      - Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **OR**
      - Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
      - Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **OR**
  - Used as subsequent therapy; **AND**
    - Used for one of the following:
      - Patients who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon-14 skipping; **OR**
      - Patients who are positive for one of the following molecular biomarkers AND received prior targeted therapy**§**: EGFR S768I, L861Q, and/or G719X mutation; **AND**
      - Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **OR**
      - Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
      - Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **OR**
  - Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy; **AND**
    - Used as a single agent following a first-line regimen with durvalumab and tremelimumab plus chemotherapy; **OR**

- Used in combination with pemetrexed following a first-line regimen with durvalumab, tremelimumab, pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology

***** *Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2) via repeat biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*
§ *Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use*

Small Cell Lung Cancer (SCLC) † ‡ Φ [1,3,7,8,10,24]

- Patient has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin; **OR**
- Patient has limited stage disease (LS-SCLC); **AND**
  - Used as a single agent therapy; **AND**
  - Used if disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) † ‡ Φ [1,3,14,18]

- Used in combination with cisplatin and gemcitabine; **AND**
  - Used as primary treatment for unresectable, resected gross residual (R2), locally advanced, or metastatic disease; **OR**
  - Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant therapy; **OR**
  - Used as neoadjuvant therapy for resectable locoregionally advanced disease *(**<u>NOTE:</u> Only applies to Gallbladder Cancer)* **Ω**; **AND**
    - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
    - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
    - Patient has mass on imaging

Hepatocellular Carcinoma † ‡ Φ [1,3,11,12,15]

- Used as first-line therapy in combination with tremelimumab; **AND**
  - Patient has unresectable disease **†**; **OR**

- Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **OR**

- Used as first-line therapy as a single agent; **AND**
  - Patient has liver-confined, unresectable disease and is deemed ineligible for transplant; **OR**
  - Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy

Ampullary Adenocarcinoma ‡ Ω [3]

- Used as first-line therapy in combination with gemcitabine and cisplatin; **AND**
- Patient has good performance status (i.e., ECOG 0-1, with good biliary drainage and adequate nutritional intake); **AND**
- Used for metastatic pancreatobiliary or mixed type disease

Cervical Cancer ‡ Ω [3,17,27e]

- Patient has small cell neuroendocrine carcinoma of the cervix (NECC); **AND**
  - Used as first-line therapy or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; **AND**
    - Used in combination with etoposide and either cisplatin or carboplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin

Esophageal Cancer and Esophagogastric Junction Cancer ‡ (Ω Esophageal Cancer only) [3,19,20]

- Used as neoadjuvant therapy in combination with tremelimumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for patients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease

Gastric Cancer ‡ [3,19,20]

- Used as neoadjuvant therapy in combination with tremelimumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in patients who are medically fit for surgery

Endometrial Cancer † ‡ [1,21]

- Patient has mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used in combination with carboplatin and paclitaxel, and continued as single agent maintenance therapy; **AND**
  - Used for primary advanced stage III-IV disease †; **OR**
  - Used as adjuvant treatment for stage III-IV endometrioid adenocarcinoma **Ω**; **OR**
  - Used as first-line therapy for recurrent disease **‡**; **AND**
    - Patient does not have isolated metastases; **OR**
  - Used as subsequent therapy for recurrent disease **‡ Ω**

Urothelial Carcinoma (Bladder Cancer) ‡ [3,25,26]

- Patient has muscle invasive bladder cancer (MIBC); **AND**
- Patient has stage II (cT2, N0) or IIIA (cT3, N0; cT4a, N0; cT1-4a, N1) disease; **AND**
  - Used in combination with cisplatin and gemcitabine as neoadjuvant therapy prior to radical cystectomy; **OR**
  - Used as a single-agent as adjuvant therapy following radical cystectomy; **AND**
    - Patient received initial therapy with durvalumab, cisplatin, and gemcitabine

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/CompanionDiagnostics*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Ω *Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria Δ [1,3]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, pancreatitis, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; **AND**

Hepatocellular Carcinoma [27]

- Cases for patients with HCC who use treatment as part of Single Tremelimumab Regular Interval Durvalymab (STRIDE) and experience disease progression but who are clinically stable and still deriving clinical benefit will be reviewed on a case-by-case basis.

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,7,8,12,17-18,20,23,26]

Indication	Dose
Non-Small Cell Lung Cancer (NSCLC)	**Single Agent as Consolidation Therapy:** • Weight ≥30 kg: Administer 10 mg/kg intravenously every 14 days OR 1,500 mg intravenously every 28 days until disease progression or unacceptable toxicity • Weight <30 kg: Administer 10 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity • ***NOTE:*** *Use as consolidation therapy for unresectable stage II-III disease may continue up to a maximum of 12 months in patients without disease progression or unacceptable toxicity.* **Neoadjuvant and Adjuvant Therapy for Resectable Disease** Neoadjuvant Therapy: • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy* every 21 days for up to 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy* every 21 days for up to 4 cycles prior to surgery or until

	disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity Adjuvant Therapy: • Weight ≥30 kg: Administer 1,500 mg intravenously as a single agent every 28 days for up to 12 cycles after surgery or until recurrence or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously as a single agent every 28 days for up to 12 cycles after surgery or until recurrence or unacceptable toxicity ***Note:** Refer to the Prescribing Information for the agent used in combination with Imfinzi dosing information.* **In Combination with Tremelimumab* and Platinum-Based Chemotherapy§:** • Weight ≥30 kg: Administer 1,500 mg intravenously every 21 days x 5 cycles, followed by a maintenance dose of 1,500 mg every 28 days thereafter, until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously every 21 days x 5 cycles, followed by a maintenance dose of 20 mg/kg every 28 days thereafter, until disease progression or unacceptable toxicity ***Note:** Refer to the Prescribing Information for tremelimumab dosing information* ***§** If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of tremelimumab (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with durvalumab, every 4 weeks.*
Small Cell Lung Cancer (SCLC)	**Extensive Stage Disease:** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 10 mg/kg as a single agent every 14 days thereafter, until disease progression or unacceptable toxicity ***Note**: Patients may receive up to 2 additional cycles in combination with chemotherapy based on response and tolerability after the initial 4 cycles (6 cycles of combination therapy in total)* [8] **Limited Stage Disease:** • Weight ≥30 kg: Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity ***Note:** Treatment may continue up to a maximum of 24 months in patients without disease progression or unacceptable toxicity.*
Hepatocellular Carcinoma	**Single Agent:**

	Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity **STRIDE (Single Tremelimumab Regular Interval Durvalumab):** • Weight ≥30 kg: Administer 1,500 mg intravenously following a single dose of tremelimumab* at Day 1 of Cycle 1, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously following a single dose of tremelimumab* at Day 1 of Cycle 1, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity ***Note:** Refer to the Prescribing Information for tremelimumab dosing information*
Biliary Tract Cancers	**Neoadjuvant Therapy (Gallbladder Cancer only):** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy every 21 days for 2 to 6 months • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days for 2 to 6 months **Primary or Recurrent Therapy:** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity
Ampullary Adenocarcinoma	Administer 1,500 mg intravenously in combination with gemcitabine and cisplatin every 21 days for up to 8 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity
Cervical Cancer	**Weight ≥30 kg:** Administer 1,500 mg intravenously in combination with chemotherapy every 21 days x 4 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity **Weight <30 kg:** Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days x 4 cycles, followed by a maintenance dose of 10 mg/kg as a single agent every 14 days thereafter, until disease progression or unacceptable toxicity
Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancer	Administer 1,500 mg intravenously on Day 1, 29, 57 for 12 weeks preoperatively for 1 cycle only

<table>
<tr><td>Endometrial Cancer</td><td><u>Weight ≥30 kg</u>:
Administer 1,120 mg intravenously in combination with carboplatin and paclitaxel every 21 days for 6 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity
<u>Weight <30 kg</u>:
Administer 15 mg/kg intravenously in combination with carboplatin and paclitaxel 21 days for 6 cycles, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</td></tr>
<tr><td>Urothelial Carcinoma (Bladder Cancer)</td><td><u>Neoadjuvant Therapy</u>:
• Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy* every 21 days for 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity
• Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy* every 21 days for up to 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity
<u>Adjuvant Therapy</u>:
• Weight ≥30 kg: Administer 1,500 mg intravenously as a single agent every 28 days for up to 8 cycles after surgery or until recurrence or unacceptable toxicity
• Weight <30 kg: Administer 20 mg/kg intravenously as a single agent every 28 days for up to 8 cycles after surgery or until recurrence or unacceptable toxicity
*<u>Note</u>: Refer to the Prescribing Information for the agents used in combination with Imfinzi dosing information.</td></tr>
<tr><td colspan="2"><u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u>
• Patient weight < 30 kg: Use 10 mg/kg dosing
• Patient weight ≥ 30 kg and <75 kg: Use 20 mg/kg dosing
<table><tr><th>Dosing (mg/kg)</th><th>Weight (kg)</th><th>Dose (mg)</th></tr><tr><td rowspan="13">20</td><td><73</td><td>1340</td></tr><tr><td><72</td><td>1320</td></tr><tr><td><67</td><td>1220</td></tr><tr><td><66</td><td>1200</td></tr><tr><td><60</td><td>1100</td></tr><tr><td><59</td><td>1080</td></tr><tr><td><55</td><td>1000</td></tr><tr><td><53</td><td>980</td></tr><tr><td><52</td><td>960</td></tr><tr><td><47</td><td>860</td></tr><tr><td><46</td><td>840</td></tr><tr><td><40</td><td>740</td></tr></table></td></tr>
</table>

		<39	720
		<34	620
		<33	600

- Patient weight ≥75 kg: Use 1500 mg flat dosing

Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

VI. Billing Code/Availability Information

HCPCS Code:

- J9173 – Injection, durvalumab, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Imfinzi 120 mg/2.4 mL single-dose vial: 00310-4500-xx
- Imfinzi 500 mg/10 mL single-dose vial: 00310-4611-xx

VII. References (STANDARD)

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of other and unspecified parts of biliary tract
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus

ICD-10	ICD-10 Description
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder
C7A.1	Malignant poorly differentiated neuroendocrine tumors

ICD-10	ICD-10 Description
D09.0	Carcinoma in situ of bladder
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.42	Personal history of malignant neoplasm of other parts of uterus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC